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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/441,857	11/18/99	DUFFY H	52494/2202

026646
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HM22/1106

EXAMINER	
CANELLA,K	
ART UNIT	**PAPER NUMBER**
1642	12

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/441,857	Duffy et al
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-80* is/are pending in the applica

4a) Of the above, claim(s) *5, 6, 13-17, 21-29, 31-33, 37-40, 42-54, 58-61, 63-69,* is/are withdrawn from considera

5) ☒ Claim(s) *1-3, 20, and 70* is/are allowed.

6) ☒ Claim(s) *4, 7-12, 18, 19, 30, 34-36, 41, 55-57, and 62* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

2. Claim 4 has been amended. Claims 1-80 are pending. Claims 5, 6, 13-17, 21-29, 31-33, 37-40, 42-54, 58-61, 63-69 and 71-80 remain withdrawn from consideration. Claims 1-4, 7-12, 18-20, 30, 34-36, 41, 55-57, 62 and 70 are under consideration.

3. The rejection of claims 1-4, 7-12, 18-20, 30, 34-36, 41, 55-57, 62 and 70 under 35 U.S.C. 112, second paragraph is withdrawn.

4. The rejection of claims 4 and 7-12, 18, 19, 30, 34-36, 41, 55-57 and 62 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic fragments consisting of SEQ ID NO:19-24 and the isolated nucleic acids of SEQ ID NO:7, 10 and 11 and polynucleotides encoding SEQ ID NO:12, does not reasonably provide enablement for additional immunogenic fragments derived from SEQ ID NO:12 and undisclosed polynucleotides which hybridize to SEQ ID NO:7, 10 and 11 or undisclosed polynucleotides which hybridize to the polynucleotides encoding SEQ ID NO:12, is maintained for reasons of record.

Applicant argues that the specification is fully enabling for immunogenic fragments of wth3 as the specification identifies fragments unique to wth3 in figure 2, and the specification on page 21, discloses properties of peptides useful for obtaining antigen-specific antibodies. Applicant further argues that the range of useful epitopes is not limited by antigenicity in a host organism, as antibodies can be obtained by phage display and protein fusions. This has been considered but not found persusaive. Firstly, examination of figure 2 indicates that it is an alignment of the wth3 protein against the rab6 protein. A comparison against a single protein

cannot allow one of skill in the art to determine a unique fragment of the wth3 protein with respect to all possible proteins in a cell. Secondly, page 21 of he specification of the specification provides only general directions for screening antibodies, but does not identify any fragments from wth3 that have resulted in useful antibodies for the detection of the expression of the wth3 protein. Seaver (Genetic Engineering News 1994 Vol 14, No 14: pages 10 and 21) teaches that selection of the antibodies for clinical diagnosis requires work with actual clinical specimens to ensure selection of a monoclonal antibody that has high sensitivity and specificity necessary for clinical diagnosis (see fourth column, first full paragraph) as a cell may contain structurally related substances of the target to be detected.

Applicant argues that the specification is fully enabling for nucleic acids which hybridize to wth3 but not to rab6. However, claim 18 is broadly drawn to nucleic acids comprising 15 nucleotides of SEQ ID NO:10 which hybridizes under stringent conditions to a nucleic acid segment of wth3 as opposed to a nucleic acid segment of a rab6 gene. Given the broadest reasonable interpretation these claims read on full length genes comprising 15 nucleotides of SEQ ID NO:10, which would hybridize to an oligomer of wth3 but not to an oligomer of rab6.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
November 4, 2001